prior to mobilization and progression free survival as well as overall survival. **Conclusion:** We conclude that 1) degree of plasma cell BM infiltration before mobilization did not predict for transplant outcomes and 2) increased plasma cell BM infiltration before mobilization adversely affect the efficiency of stem cell mobilization. Thus, pre-transplant cytoreductive therapy improves stem cell collection efficiency but did not affect the transplant outcomes.

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ID/KLH ACTIVE IMMUNOTHERAPY (FAVID®) FOLLOWING HIGH DOSE THERAPY (HDT) AND AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT) FOR NON-HODGKIN'S LYMPHOMA (NHL)

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Sixteen patients with NHL were treated in a pilot study evaluating the feasibility, safety and potential efficacy of patient specific idiotype immunization (Id/KLH Active Immunotherapy) following HDT and ASCT. FavId was administered along with GM-CSF. Two patients continue in active treatment; 1 mantle cell lymphoma (MCL) and 1 transformed NHL (TL) and are not reported here. Of the remaining 14 patients, 8 had MCL, 4 had follicular lymphoma (FL), 1 had small lymphocytic lymphoma (SLL) and 1 had TL. The median number of prior regimens for all patients was 3 (range 1-10). For MCL patients, the median number of prior regimens was 2.5 (range 1-4) which included CHOP and hyperCVAD +/- rituximab (R). FL patients received a variety of regimens including fludarabine, CVP, CHOP, R alone or in combination and Zevalin. All MCL and FL patients received HDT with BEAM except 1 who received CEB. The TL patient received Bexxar, Cy/VP-16. Idiotype immunizations were begun 3 months following HDT/ASCT. Of the 6 patients with MCL who achieved a CR following transplant, 5 remain in continuing CR (CCR) between 27 and 60 months post-transplant. The 6th patient relapsed after 40 months. Of the 3 patients with FL who obtained a CR, 2 continue in CR at 41-58 months post-transplant. The 3rd FL patient died from MDS at 34 months. Of the 5 MCL patients with a continuing CR, 4 developed cellular anti-Id and anti-KLH responses and one was not tested. The patient who relapsed after 40 months also had both anti-Id and anti-KLH cellular responses. Of the 3 FL patients who obtained a durable CR, 2 developed anti-Id and anti-KLH cellular responses and the 3rd was not tested. Id/KLH Active Immunotherapy was well tolerated with injection site reactions being the most commonly reported adverse effects. GM-CSF related myalgias were also commonly reported. We conclude that Id/KLH Active Immunotherapy following HDT and ASCT for MCL and FL is feasible, safe, associated with idiotype specific immune responses and may be associated with prolonged remissions, even in patients heavily pretreated with very immunosuppressive regimens.

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USE OF A NOVEL ORGANIC ARSENIC (ZIO-101) AFTER AUTOTRANSPLANTS FOR MULTIPLE MYELOMA

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Background Autotransplants are commonly used to treat multiple myeloma; unfortunately most recipients relapse. Subsequent therapy is often difficult because of limited bone marrow reserve. ZIO-101, a new organic arsenic, is active against human myeloma cell lines *in vitro* and in scid mice with human myeloma xenografts. ZIO-101 is active in phase-1 trials in multiple myeloma and has little bone marrow toxicity. Because of these features, ZIO-101 is a good candidate for therapy of multiple myeloma after an autotransplant.

Method Phase-1 and -2 trials in persons with multiple myeloma. Pharmacokinetic (PK) studies.

Subjects N=13. Median age, 57 y (range, 41-78 y); 5 were male. All had advanced myeloma: median N prior therapies, 6 (range, 2-12). 6 received ≥1 prior autotransplants.

Dosimetry 4 cohorts received 25 courses of ZIO-101 with a starting dose of 78 mg/me2/d IV and a maximum administered dose (MAD) of 420 mg/me2/d. 2 schedules were studied: (1) daily for 5 consecutive d every 4 w; and (2) twice weekly for 3 w every 4 w. Median N cycles was 2 (range, 1-10). Adverse events at doses < 300 mg/me2/d were modest and there was no clinically-important bone marrow toxicity or QTc-prolongation. Estimated maximum tolerated dose (MTD) is 300-420 mg/me2/d.

Activity Activity was seen including subjects receiving a prior autotransplant. Details will be presented.

PK Studies at 420 mg/me2/d showed a tmax = 1 h (SD ± 0.9), Cmax = 1.06 μg/mL (SD ± 0.07 μg/mL), t1/2 = 17.8 h (SD ± 1.4 h) and AUC0-∞ = 25.9 μg · h/mL (SD ± 0.8 μg · h/mL).

Conclusions ZIO-101 is safe in persons with multiple myeloma at doses ≤300-420 mg/me2/d (MTD) and may be especially useful posttransplant because of modest bone marrow suppression.

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IMPROVED OUTCOME OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) IN FIRST REMISSION (CR1) AFTER HEMATOPOIETIC STEM CELL TRANSPLANTATION

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Introduction: MCL, accounts for 5% of non-Hodgkin lymphoma and is characterized by t(11;14) translocation leading to Cyclin D1 over expression. It is currently considered incurable, with a median overall survival (OS) of 3 to 4 years from diagnosis. Results of hematopoietic stem cell transplant (HSCT) are mixed, with earlier studies showing no survival advantage over conventional chemotherapy, but more recent studies, suggesting better outcome. The optimal timing of HSCT for patients (pts) with MCL is not known.

Methods: Between 2/1994 and 5/2006, 70 consecutive pts with MCL underwent an autologous (auto) (n = 56) or allogeneic (allo) [n = 14 (11-myeloablative; 3-reduced intensity regimens-RIC)]. Most pts had stage IV disease 50/70 (71%). 46/70 (66%) pts had bone marrow (BM) involvement. Conditioning regimen for auto HSCT consisted mainly of CBV (cyclophosphamide, BCNU and etoposide). Allo HSCT regimens included ablative (cyclophosphamide/VP16 ± TBI); or RIC (fludarabine/busulfan or fludarabine/TBI). GVHD prophylaxis consisted of cyclosporine (CSA) and methotrexate or CSA/mycophenolate mofetil. 56 pts received BM, 10-peripheral blood (PB) and 4 (BM/PB).

Results: Median age at transplant was 56 years (yrs) (range 35-67). Median follow up was 2.1 yrs (range, 0.01-9.1). 50% of the pts had at least 2 prior therapies prior to transplant. 55/70 pts had a response after transplant (52-complete remission, and 3 partial responses). 4/70 pts had no response and progressed. 35 pts are alive (27-autologous; 8-allogeneic), of which 17 pts relapsed. 35 patients are dead: progressive disease, 23; sepsis/infection, 5; secondary malignancy, 2; pulmonary embolism, 1; and other causes, 4. Median OS was 3.5 yrs (95% CI 2.4 to 4.6) with no significant difference between auto and allo (median not reached) pts (P = 0.78). Median progression free survival (PFS) was 3.5 yrs (95% CI 0.6 to 6.3), and was not different for auto or allo (median not reached) HSCT (P=0.82). 25/70 (36%) patients underwent HSCT (auto-24, allo-1) in CR1. OS of these patients was superior compared to pts transplanted later in their disease course (not reached vs. 2.5 yrs, P=0.023).

Conclusion: Patients transplanted in CR1 have a better overall survival compared to being transplanted later in the disease course. Pts not achieving CR1 or presenting with recurrence of disease should be considered for early transplant. The optimal type of transplant in these patients needs to be further validated.